

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor's Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SMB

| | |
|------------------|----------------|
| Display Date | <i>12-4-4</i> |
| Publication Date | <i>12-501</i> |
| Certifier | <i>S Reese</i> |

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor's address for Merial Ltd.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION: Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830-3077, has informed FDA of a change of sponsor's address to 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 22 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redefegated to the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by revising the entry for “Merial Ltd.” and in the table in paragraph (c)(2) by revising the entry for “050604” to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

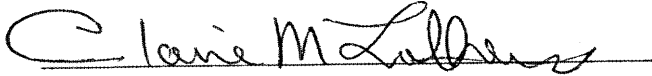
| Firm name and address | Drug labeler code |
|---|-------------------|
| Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640. | 050604 |

(2) * * *

| Drug labeler code | Firm name and address |
|-------------------|---|
| 050604 | Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640. |

Dated: 11/15/01
November 15, 2001

cv0194



Claire M. Lathers,
Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

